REMARKS

This Communication accompanies the enclosed Request for Continued Examination of the above application. The remarks herein are provided in reply to the Office Action dated February 18, 2004. Claims 1-5 and 13 are currently under examination in the Application.

Applicants wish to thank the examiner for the signed PTO-1449 forms that were sent with the Office Action August 8, 2003. Applicants note however, that Reference AA, U.S. Patent No. 5,801,005 (Cheever *et al.*), was not acknowledged. Accordingly, enclosed is a PTO-1449 form listing this reference and enclosing a copy of said reference. Applicants respectfully request that the Examiner acknowledge that the listed reference has been considered by returning a copy of the initialed form with the next communication mailed to Applicants.

Claims 2-5 stand rejected under 35 USC § 112, first paragraph, because the specification allegedly lacks written description support for the claimed invention. According to the Examiner, the limitation of an isolated polypeptide comprising SEQ ID NO: 3 and consisting of no more than amino acid residues 975-1209 of human Her-2/neu has no clear support in the specification and claims as filed. More particularly, the Examiner acknowledges that the specification contains support for an epitope contained within the 235 amino acid fragment beginning at position 975 wherein the epitope resides at positions 1021-1030, designated as SEQ ID NO: 3. However, the Examiner alleges that although the cited support is supportive of a fragment consisting of 235 amino acid residues from amino acid residues 975-1209 of SEQ ID NO: 2, it is not supportive of the broadly claimed fragments of the 235 amino acid fragment consisting of 10 through 235 amino acid residues.

Applicants respectfully traverse this rejection. The standard for written description is not whether explicit literal support is present, but whether the skilled artisan would recognize, in view of the disclosure as originally filed, that Applicants were in possession of the invention now being claimed. "[*I*]*psis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." (*Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895, Fed. Cir. 1996).

The currently claimed invention is directed to an isolated polypeptide composition, said polypeptide comprising the naturally processed epitope of SEQ ID NO: 3 and consisting of no more than amino acid residues 975-1209 of human Her-2/neu. The Examiner acknowledges support for an isolated polypeptide consisting of 235 amino acid residues from 975-1209 of human Her-2/neu, but alleges that there is a lack of support for any fragment of such a polypeptide, *e.g.*, a fragment comprising SEQ ID NO: 3 and consisting of no more than residues 975-1209 of Her-2/neu.

Applicants submit that upon a complete review and consideration of the specification as originally filed, the skilled artisan would readily appreciate that Applicants' disclosure does indeed describe and encompass Her-2/neu polypeptides and fragments thereof as currently claimed. The specification, for example, at page 9, lines 16-19, discloses the following:

> A polypeptide may be an entire protein, or a subsequence thereof. Particular polypeptides of interest in the context of this invention are amino acid subsequences comprising epitopes, *i.e.* antigenic determinants substantially responsible for the immunogenic properties of a polypeptide and being capable of evoking an immune response. (page 9, lines 24-28)

Thus, the specification describes that a polypeptide may be a subsequence of the human Her-2/neu polypeptide and that particular polypeptides of interest include subsequences of Her-2/neu which comprise immunological epitopes.

The specification further describes the following, at page 10, lines 16-19:

> Particularly preferred polypeptide compositions in this regard are from the ICD region of the Her-2/neu protein, preferably containing some or all of the region from about amino acids 676-1255 of SEQ ID NO: 2, and more preferably comprising at least the naturally processed HLA-B44-restricted Her-2/neu epitope set forth in SEQ ID NO: 3. (page 10, lines 16-19)

The specification thus describes quite clearly that certain polypeptides of the invention contain some or all of the Her-2/neu ICD region and, furthermore, that such polypeptides also preferably comprise the naturally processed epitope of SEQ ID NO: 3.

Accordingly, to assert that the artisan of ordinary skill would not understand or recognize that Applicants were in possession of the claimed invention fails to consider Applicants' disclosure in its entirety and, moreover, belies the level of knowledge and understanding of the individual skilled in this art. To accept the Examiner's position would require that the skilled individual reach the conclusion that only a polypeptide of amino acids 975-1209 was in Applicants' possession, but that fragments of this polypeptide comprising SEQ ID NO: 3 were not, despite the explicit disclosure that SEQ ID NO: 3 was identified by Applicants as a T-cell epitope contained within amino acids 975-1209, and despite the further disclosure that polypeptides containing some or all of a Her-2/neu ICD region, while also comprising the claimed epitope of SEQ ID NO: 3, represent preferred compositions of the invention.

In light of the disclosure in the specification as originally filed, Applicants submit that it would be easily appreciated by the skilled artisan that the claimed polypeptides comprising the epitope of SEQ ID NO: 3 and consisting of no more than amino acid residues 975-1209 of Her-2/neu are encompassed by the disclosed invention and can be used according to Applicants' disclosure. Reconsideration of this rejection is respectfully requested.

Claims 2-5 and 13 stand rejected under 35 USC § 103 as allegedly being unpatentable over US 2002/0177567, in view of Harlow and Lane (of record) or Johnston and Thorpe (of record). According to the Examiner, US 2002/0177567 teaches a 59 amino acid fragment of human Her-2/neu, SEQ ID 5, which allegedly has 100% identity to a portion of SEQ ID NO: 2, within the range of amino acids 975-1209, which comprises SEQ ID NO: 3, wherein the polypeptide consists essentially of SEQ ID NO: 3. The Examiner further states that the cited reference teaches that SEQ ID NO: 5 is a fragment of the phosphorylation domain of Her-e/neu and that the specificity and uniqueness of the domain makes it particularly preferred as a tumor vaccine. The Examiner acknowledges that the reference does not teach a composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier and comprising an immunostimulant. However, according to the Examiner, it would have been obvious to use the polypeptide in combination with a pharmaceutically acceptable carrier, in view of the teachings of Johnston and Thorpe of formulating a protein with PBS, and in view of

the teachings of Harlow and Lane of using adjuvants to enhance an immune response to a soluble antigen.

Applicants respectfully traverse this rejection. A careful review of US 2002/0177567 reveals that the teachings of this reference as a whole have not been properly considered by the Examiner. Rather, the Examiner has based a conclusion of obviousness on a selective and incomplete interpretation of the reference. Applicants acknowledge, as asserted by the Examiner, that the cited reference describes a polypeptide fragment of human Her-2/neu within the range of amino acid residues 975-1209, which comprises SEQ ID NO: 3. However, the reference does not teach an isolated polypeptide "consisting of no more than amino acid residues 975-1209 of human Her-2/neu", as claimed by Applicants. Rather, the cited reference teaches that the polypeptide described as SEQ ID NO: 5 is used in fusion with a separate and distinct polypeptide, but never alone as an isolated polypeptide by itself. In fact, the entire disclosure of the cited reference relates specifically to such fusion polypeptides. The cited reference thus cannot render obvious Applicants claimed polypeptide consisting of no more than residues 975-1209 of human Her-2/neu when the reference explicitly requires that the described SEQ ID NO: 5 be used in fusion with another polypeptide. The cited reference cannot teach away from the claimed invention in this manner and simultaneously render the invention obvious to the skilled artisan.

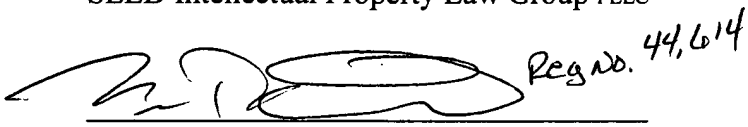
Moreover, the secondary references cited by the Examiner fail to remedy the above-noted deficiencies with respect to US 2002/0177567, particularly when these secondary references also offer nothing to teach or suggest a polypeptide comprising SEQ ID NO: 3 and consisting of no more than amino acid residues 975-1209, or the use of such polypeptides in combination with an adjuvant or carrier. Reconsideration of this rejection is respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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